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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Applicant : Schutt et al.
Appl. No. : 09/218,213
Filed : December 22, 1998
For : STABILIZED
PREPARATIONS FOR USE IN
NEBULIZERS
Examiner : TRAN, S.

) Group Art Unit 1615
)
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) June 10, 2002 (Date)
) *Karen J. Moir*
) *Kathy Honnold*
) Karen Moir

APPELANT'S REPLY
BRIEF UNDER 37 C.F.R.
1.192

Assistant Commissioner for Patents
Washington D.C. 20231

Sir:

Enclosed is Appellant's Reply Brief filed under 37 C.F.R. 1.192 in response to the
Examiner's Answer mailed April 10, 2002.

Remarks

The following remarks are offered to help highlight the technology at issue and crystallize the issues for consideration by the Board. As stated in the Summary section of Applicant's Appeal Brief, the present invention relates to methods and systems for administering stabilized dispersions via nebulization to the respiratory tract. Nebulizers work by forming aerosols by converting bulk liquid into small droplets suspended in a breathable gas. The bulk liquid or respiratory dispersion in the case of the present invention is a particulate suspension of perforated microstructures suspended in a fluorochemical suspension medium. Once nebulized, the perforated microstructures are inhaled by a patient during regular respiration without requiring medical supervision or in-patient facilities or care. Unlike prior art formulations, the present

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invention employs novel techniques to reduce attractive forces between the dispersed constituents and to reduce density fluctuations in the stabilized dispersion thereby retarding degradation of the preparation by flocculation, sedimentation, or creaming. The stable dispersion of the present invention thereby reduces dosing incongruities thereby facilitating drug delivery.

The rejection maintained by the Examiner seeks to modify a closed-circuit, liquid ventilation apparatus with means for introducing a medicament to the pulmonary system (Faithful et al. 6,041,777) by incorporating teachings of the prior art related to particle morphology and materials useful in administering particulate aerosols to the pulmonary system in inspired gases (Hanes et al. 5,855,931). As set forth by the Examiner, the reason for this modification is to improve the aerosolization of the particles and to reduce particle agglomeration.

There is absolutely no reason for combining the references in the manner proposed by the Examiner. The Faithfull et al. invention is concerned with administering a breathable liquid to the pulmonary system as part of a closed-circuit ventilation therapy. Such therapy is performed in the hospital under medical supervision and care. Medicament may be introduced into the breathable liquid such as with a nebulizer as indicated by the Examiner. However, since any such medicament is introduced into the breathable liquid which is circulated through the lungs with the liquid ventilation apparatus of Faithfull et al., the aerosol characteristics of the medicament does not dictate whether the medicament will successfully navigate the respiratory system (and reach the deep lung) Such aerosol characteristics are relevant to inhalation in inspired gases as in Hanes et al. and are not applicable to pulmonary administration of medicament dispersed in a liquid administered to the lung in a closed-circuit, liquid ventilation apparatus. As such, there is absolutely no reason for one of ordinary skill in the art to look to the teachings of Hanes et al. in order to improve aerosol characteristics of the medicament introduced during the liquid ventilation therapy of Faithfull et al.


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Conclusions

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of the claims that are presented on appeal. None of the cited references, individually or in combination, describe or suggest the methods and systems of the present invention. Accordingly, Appellants respectfully request that the Board reverse the Examiner's rejection of the claims on appeal.

Respectfully submitted,

Dated: 6/10/02

By: 

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/218,213	
	Filing Date	December 22, 1998	
	First Named Inventor	Ernest G. Schutt	
	Group Art Unit	1615	
	Examiner Name	S. Tran	
Total Number of Pages in This Submission	11	Attorney Docket Number	0055.00

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